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microstructure of the Teflon surface would be expected to be inherently present in the Teflon surface of Niino or Kuper.

Office Action of April 23, 2002, at 2. When the Niino et al. and Kuper et al. references are carefully reviewed, however, it becomes clear that they are directed at completely different precursor materials from the present invention and employ different treatment processes. These differences will necessarily produce completely different final products. As such, neither of these references either teaches or suggests the present invention as claimed.

As is described in the present application, the present invention employs an *expanded* polytetrafluoroethylene (PTFE) as its precursor material, such as that described in United States Patent 3,953,566. Expanded PTFE differs from other forms of PTFE in that it has a microstructure of polymeric nodes interconnected by fine polymeric fibrils. See Application, at 7. This material has numerous properties that makes it especially suitable for use as an implantable device.

Using this expanded PTFE precursor material, the present invention then modifies the node and fibril microstructure to create unique nodal structures. Specifically, by treating the surface of the expanded PTFE with a laser in the manner described in the present application, it has been determined that fibrils surrounding the treated nodes are removed while the nodes are altered so that they take on completely novel shapes and properties. As is explained and shown in the present application, nodes treated in this manner take on a free-standing "gnarled" appearance.

Among the benefits of the present invention is that the gnarled nodes can be used to create an excellent roughened surface on the expanded PTFE material so as to improve in-growth properties for the material when used as an implant. Additionally, this roughened surface can be easily formed into a wide variety of surface patterns to aid in surface identification and other benefits. Even more surprisingly, the gnarled nodes tend to have a length longer than the depth of the material from which they have been formed.

None of the references of record in any way teaches or suggests that this form of structure can be formed using an expanded PTFE material.

The Niino et al. reference employs an excimer laser to cause a chemical reaction to occur to make PTFE hydrophilic. See Niino et al., at 259. Nothing in this article in any way suggests that the PTFE material used is an *expanded* PTFE or that Niino et al.'s PTFE has any node and fibril microstructure. Without the presence of a node-and-fibril microstructure in the starting material, the Niino et al. process cannot possibly obtain the final nodal structure defined and claimed in the present application. Moreover, the Niino et al. reference specifically teaches that

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only a chemical change is sought through their process – with no mechanical modification of the material. Niino et al. state: "...the mechanical property of PTFE is not hurt by the laser processing and the modified layer has similar mechanical strength to PTFE." *Id.* at 260. This plainly is not what occurs with the process of the present invention in that the mechanical properties of applicant's material surface are thoroughly altered in the process of the present invention. The present invention removes the fibrils surrounding each modified node and significantly changes the nodes themselves. As such, nothing in the Niino et al. patent in any way teaches or suggests the material achieved with the present invention as claimed.

Likewise, the Kuper et al. reference also employs a non-expanded PTFE in its process. Kuper et al. is directed to ablating undoped PTFE with a laser. The reference contains no teaching or suggestion that expanded PTFE is employed or that a node and fibril structure is present in its material. On the contrary, the Kuper et al. article teaches that its starting material is a conventional, commercially available full-density PTFE material – which would not have a node-and-fibril structure. Specifically, Kuper et al. teaches using "4 mm-thick commercial Teflon sheets" with a stated density of "2.15 g/cm³." Kuper et al., at 4. As is known, a density of 2.15 g/cm³ is indicative of full-density PTFE material that has no porosity. Review of the scanning electromicrographs shown in Figures 1 and 2 of Kuper et al. shows no nodes or fibrils in their material, much less the particular nodal structure claimed in the present application. The Kuper et al. reference is devoid of any teaching or suggestion of the present invention.

Thus, neither the Niino et al. reference nor the Kuper et al. reference employs an expanded PTFE precursor material, which is necessary to achieve the final structure of the present invention. Additionally, neither of these references provides any teaching or suggestion of how a particular laser treatment of expanded PTFE might achieve the surface properties provided by the present invention.

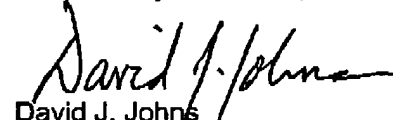
In order to clarify these distinctions over the two cited references, applicant has amended each of the independent claims to emphasize that an *expanded* PTFE is employed to achieve the material of the present invention. Antecedent basis for this amendment is found throughout the present application. See, e.g., Application, at 3. Nothing in any of the references of record in any way teaches or suggests the material now defined by independent claims 1 (twice amended), 2 (twice amended), and 10 (twice amended). Additionally, the dependent claims further define new and non-obvious improvements over all of the references of record.

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CONCLUSION

For the foregoing reasons, each of claims 1 (twice amended), 2 (twice amended), 3 (amended), 4 (amended), 5-7, 10 (twice amended), and 12-27 is new and non-obvious over all of the cited references. Applicant respectfully requests reconsideration and allowance of all of the claims in the present application. If any questions remain, applicant requests an interview before issuance of the next Office Action.

Respectfully submitted,



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Date: July 22, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1, 2, and 10 have been amended as follows:

1. (twice amended) A material comprising:
 - a surface comprising expanded PTFE having a node and fibril microstructure;
 - the surface having a number of node clusters, said node clusters comprising multiple nodes interconnected by fibrils, and gnarled nodes situated between the node clusters; and
 - said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length.
2. (twice amended) A material comprising:
 - a surface comprising expanded PTFE having a node and fibril microstructure;
 - said surface comprising a textured pattern having multiple ridges and valley surfaces, the ridges comprised of node clusters;
 - said node clusters comprising multiple nodes interconnected by fibrils;
 - the valley surfaces having gnarled nodes protruding therefrom; and
 - said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length.
10. (twice amended) A material comprising:
 - expanded PTFE having a node and fibril microstructure;
 - at least one node having a protruding length measured from a valley surface, the at least one node being substantially devoid of fibrils along its protruding length;
 - the at least one node being adjacent to a ridge having a height; and
 - the protruding length of the node being greater than the height of the adjacent ridge.